

REMARKS

Claims 1-2, 5-7 and 9-21 are pending. Claims 13-21 have been added. Solely to advance prosecution and without prejudice, claims 2 and 10 have been canceled. Solely to advance prosecution and without prejudice, claims 1, 3, 5 and 9-12 have been amended.

Claim 1 has been amended to delete reference to CHK and to recite “-CH(C₁₋₄ alkyl), -CH(C₃₋₆ cycloalkyl).” Support for this amendment is found, for example, in original claim 1 and on page 3, lines 6-7 of the specification. Claim 1 has also been amended to add “R₁ and R₂ are optionally CH=CH-CH=CH.” Support for this amendment is found, for example, in original claim 3 and in Table 1 of the specification at pages 28-29.

New claim 13 recites a genus of compounds in which R₁ is -C₁₋₄ alkyl, halogen, -NO₂, -OW (wherein W is -H, -CH₃, -aryl), or -SW (wherein W is -H, -CH₃, -aryl). Support for this amendment is found, for example, in original claim 1.

New claim 14 recites the species of original claim 2.

New claims 15 recites the species of original claim 2, wherein Z is hydrogen.

New claims 16-21, which depend from new claim 13, correspond to original claims 5-7 and 9-12.

Claims 1-3, 5-7 and 9-12 stand rejected. Applicants respectfully request reconsideration of the pending rejections based on the amendments and the following comments.

Claims Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-3, 5-7, and 9-12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

First, the Examiner rejects claim 1 because the recitation of “X = -CH₂ , -CHK (wherein K is -H...” is allegedly confusing. (Office Action, page 2). Applicants respectfully point out that redundant elements in a Markush group do not render a claim indefinite. See Manual of Patent Examination and Procedure (“MPEP”) § 2173.05(h) (“the Markush group, ‘selected from the group consisting of amino, halogen, nitro, chloro and alkyl’ should be acceptable even though ‘halogen’ is generic to ‘chloro.’”). However, solely to advance prosecution and without prejudice, claim 1 has been amended to delete reference to CHK and to recite “-CH(C₁₋₄ alkyl), -CH(C₃₋₆ cycloalkyl).” Therefore, the Examiner’s rejection is moot.

Second, the Examiner rejects the terms “soluble derivative” and “derivative” in claims 1, 5 and 9-12 as allegedly indefinite. Solely to advance prosecution and without prejudice, Claims 1, 5, 9 and 11-12 have been amended to delete the terms “soluble derivative” and “derivative.”

Therefore, for at least these reasons, Applicants respectfully request that the rejection of claims 1-3, 5-7, 9 and 11-12 under 35 U.S.C. § 112, second paragraph be withdrawn.

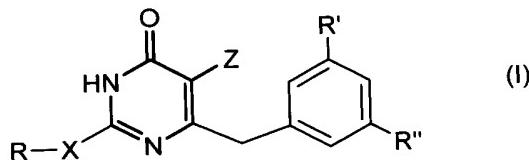
Claims Rejections under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 9, 11 and 12 under 35 U.S.C. § 112, first paragraph, because allegedly the specification does not provide enablement for preventing HIV infection. Solely to advance prosecution and without prejudice, claims 9, 11 and 12 have been amended to delete reference to “preventing” HIV infection. The claims now recite, *inter alia*, methods of treating HIV or AIDS. Therefore, the Examiner’s rejection is moot and Applicants respectfully request the rejection be withdrawn.

Claims Rejections under 35 U.S.C. § 102

A. Claims 1, 5-7 and 9-12 are not anticipated by Artico *et al.*

The Examiner has rejected claims 1, 5-7 and 9-12 under 35 U.S.C. § 102(b) as anticipated by PCT publication No. WO 96/10565 to Artico *et al.* (“Artico”). Artico discloses compounds of the formula (I)



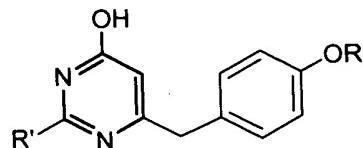
wherein X is O or S; R is C₁₋₄ alkyl or C₅₋₆ cycloalkyl; and R', R'', and Z are each independently H or C₁₋₄ alkyl.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” MPEP § 2131, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In Artico, the compounds disclosed have the limitation that the benzylic carbon is unsubstituted. In instant claim 1, the benzylic carbon must be substituted because Z cannot be hydrogen. Thus, instant claim 1 is not anticipated by Artico because Artico is missing an essential element of claim 1- substitution at the benzylic carbon.

Because claims 5-7 and 9-12 depend from claim 1, they are not anticipated by Artico. See MPEP § 2131. Therefore, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

B. Claims 1, 5-7 and 9-12 are not anticipated by Aroyan *et al.*

The Examiner has rejected claims 1, 5-7 and 9-12 under 35 U.S.C. § 102(b) as anticipated by Aroyan *et al.* ("Aroyan"). Aroyan discloses substituted (4-alkoxybenzyl)pyrimidines of the formula



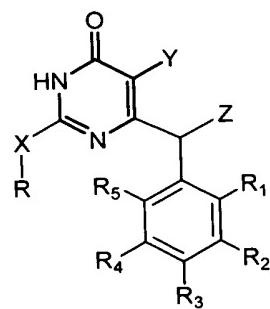
wherein R is methyl or ethyl and R' is OH, O-alkyl, SH, S-alkyl or NH₂. Aroyan does not disclose compounds in which the benzylic carbon is substituted.

Instant claim 1 recites compounds wherein the benzylic carbon must be substituted. Therefore, instant claim 1 is not anticipated by Aroyan because Aroyan does not disclose an essential element of claim 1—substitution at the benzylic carbon. Because claims 5-7 and 9-12 depend from claim 1, they are not anticipated by Aroyan. See MPEP § 2131. Therefore, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

Obviousness-Type Double Patenting Rejections

A. U.S. Patent No. 6,545,007.

Claims 1-3, 5 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-23 of U.S. Patent No. 6,545,007 ("the '007 patent"). Claims 20-23 of the '007 patent recite, *inter alia*, compositions in the form of an intra-vaginal or intra-rectal pill or suppository, comprising a compound of the formula:



wherein Z is hydrogen, C₁₋₄ alkyl, or C₃₋₆ cycloalkyl. Instant claim 1, as currently amended, recites compounds of the same formula, wherein Z cannot be hydrogen.

An obviousness-type double patenting rejection is appropriate only when the claims at issue are not “patentably distinct” from the claims of a commonly owned earlier patent. *See Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001). A claim is not patentably distinct from an earlier patent claim if the later claim is “obvious over, or anticipated by, the earlier claim.” *Id.* at 968. Applicants request withdrawal of the double patenting rejection because the instant claims are not obvious over, or anticipated by the claims of the ‘007 patent.

Instant claims 1, 3 and 5, as currently amended, recite compounds or salts thereof. None of these claims recite compositions for an intra-vaginal or intra-rectal pill or suppository. Thus, claims 1, 3 and 5 do not overlap with, and are patentably distinct from, claims 20-23 of the ‘007 patent. *See Eli Lilly & Co.*, 251 F.3d at 967.

Instant claim 10 recites a pharmaceutical composition comprising a compound of claim 1 and a carrier. Claims 20-23 do not disclose or suggest a pharmaceutically acceptable carrier. Therefore, instant claim 10 does not overlap with, and is patentably distinct from, claims 20-23 of the ‘007 patent. *See Eli Lilly & Co.*, 251 F.3d at 967.

For at least these reasons, Applicants respectfully request that the double patenting rejection of claims 1-3, 5 and 10 be withdrawn.

B. U.S. Patent Application No. 10/350,772.

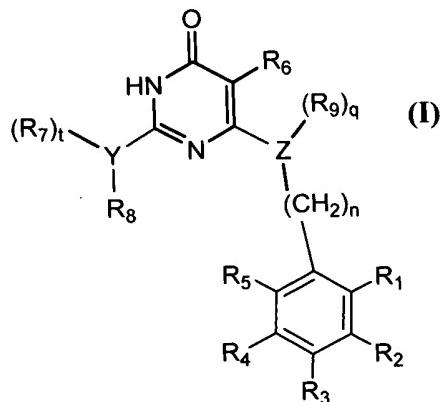
Claims 1-3, 5-7 and 9-12 are provisionally rejected under obviousness-type double patenting as being unpatentable over claims 1-15, 17-25 and 30-46 of U.S. Patent Application No. 10/350,772. Applicants request deferral of this issue until an indication of allowable subject matter in each application.

C. U.S. Patent Application No. 11/327,672.

Claims 1-3, 5-7 and 9-12 are provisionally rejected under obviousness-type double patenting as being unpatentable over claims 1-25 and 29 of U.S. Patent Application No. 11/327,672. Applicants request deferral of this issue until an indication of allowable subject matter in each application.

D. U.S. Patent Application No. 10/833,601.

Claims 1-3, 5-7 and 9-12 are provisionally rejected under obviousness-type double patenting as being unpatentable over claims 1-8 and 37-80 of U.S. Patent Application No. 10/833,601 (“the ‘601 application”). Claim 1 of the ‘601 application recites compounds of formula (I)



wherein Z is O, S, SO₂ or N. Claims 2-8 and 37-80 of the '601 application depend from claim 1. According to the claims of the '601 application, Z cannot be carbon. The instant claims, as currently amended, recite compounds wherein the 6-position of the pyrimidin-4-one ring is substituted by carbon. None of claims 2-8 and 37-80 of the '601 application recite compounds in which the 6-position of the pyrimidin-4-one ring is substituted by carbon. Thus, claim 1 does not overlap with, and is patentably distinct from, claims 2-8 and 37-80 of the '601 application. See *Eli Lilly & Co.*, 251 F.3d at 967. Instant claims 3, 5-7, 9 and 11-12 all depend from instant claim 1.

For at least these reasons, Applicants respectfully request that the double patenting rejection of claims 1, 5-7, 9 and 11-12 be withdrawn.

CONCLUSION

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

Please apply fees for the extension of time for three months (\$1,020.00) and any other charges, or any credits, to Jones Day Deposit Account No. 503013.

If the Examiner believes it would be useful to advance prosecution, the Examiner is invited to telephone the undersigned at (858) 314-1200.

Respectfully submitted,



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